

K970074

APR -3 1997

510(k) Summary

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**Applicant:**

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**Device trade/proprietary name:**

" Stabilet™"

**Device common/usual/classification name:**

Infant Radiant Warmer

**Classification:**

General Hospital and Personal Use Device, 21 CFR 880.5130 , Infant Radiant Warmer, 80FMT, Class III

**Predicate (Current) Device:**

Hill-Rom " Stabilet™" Infant Radiant Warmer, K942948

**Device Description**

The Hill-Rom Stabilet™ is a device consisting of an infrared heating element positioned over an infant to maintain the infant's body temperature by means of radiant heat. Available features include a warming/lighting module which provides heat through two stainless steel heater tubes, manual or servo heat control with a temperature monitoring sensor and temperature alarms, procedural Apgar timer, bassinet with mattress and spring loaded fold down sides, trendelenburg/reverse trendelenburg, x-ray cassette tray, retractable Mayo

tray, slide through storage drawer, resuscitation equipment, storage bin and casters with front locking brakes, optional scale and hilo feature.

**Intended Use:**

The Stabilet- Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the healthcare facility that provide neonatal and infant care.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner and its use is restricted to health care facilities.

**Design and construction:**

Both the new and predicate warmers utilize the same materials and methods of construction. The warmers are fabricated from steel, aluminum, and plastic. The submitted warmer's most highly stressed areas utilize only steel and aluminum. Plastics are used in less stressed areas. Steel and aluminum warmer components are welded or assembled with commercially available fasteners. Plastics used in less stressed areas are assembled with fasteners.

The subject warmer and predicate warmer in this submission are substantially equivalent. There is some variation in the available features of the warmers, but the variations do not significantly affect the safety or efficacy of the warmers.

This submission is a result of the introduction of several improvement modifications Hill-Rom has introduced to the existing product. The principal changes are:

**Modification of the heater lamp housing**

- Bare quartz element changed to a stainless steel element.

*The new element eliminates tube breakage as a hazard to the patient or caregiver. The electrical contacts have been changed from a spring compression socket arrangement to an insulated wire with a screw. This provides a positive locking electrical connection to the power supply.*

- One heating element to two.

- Heating element length increased from 12" to 16"
- Change parabolic reflector from pebbled to smooth to optimize irradiance pattern with new dual heating elements

*Two 375W elements centered over the bassinet replace the single 760W element in the predicate warmer. In conjunction with the increased length and the changes to the parabolic reflector, the irradiance pattern is more evenly distributed and the time required to warm the infant to the caregiver- selected skin temperature is reduced.*

#### **Height adjustability for the 1500C and 2000D.**

*This is a customer preference feature and does not impact the safety of the device to the user or patient. The heater lamp housing to bassinet surface relationship is maintained.*

#### **Quartz Halogen task light replaces the florescent task light.**

*The light is balanced to 3200°K. This more closely approximates natural ambient light and eliminates the color bias imparted by florescent lighting.*

#### **Accessories**

Resuscitation and Suction modules are offered as options on all current and previous models and the 1250C and 1500C Stabilet-. This does not represent an increased risk to the user or patient as these options are already standard features on the Predicate 2000C.

A scale option (Premarket Notification K926174) is also available on the P1500C and P2000D models.